product jurisdiction officer to reconsider the decision by filing, within 15 days of receipt of the letter of designation, a written request for reconsideration not exceeding 5 pages. No new information may be included in a request for reconsideration. The product jurisdiction officer shall review and act on the request in writing within 15 days of its receipt.

§ 3.9 Effect of letter of designation.

(a) The letter of designation constitutes an agency determination that is subject to change only as provided in paragraph (b) of this section.

(b) The product jurisdiction officer may change the designated agency component with the written consent of the sponsor, or without its consent to protect the public health or for other compelling reasons. A sponsor shall be given 30 days written notice of any proposed nonconsensual change in designated agency component. The sponsor may request an additional 30 days to submit written objections, not to exceed 15 pages, to the proposed change, and shall be granted, upon request, a timely meeting with the product jurisdiction officer and appropriate center officials. Within 30 days of receipt of the sponsor's written objections, the product jurisdiction officer shall issue to the sponsor, with copies to appropriate center officials, a written determination setting forth a statement of reasons for the proposed change in designated agency component. A nonconsensual change in the designated agency component requires the concurrence of the Principal Associate Commissioner.

[56 FR 58756, Nov. 21, 1991, as amended at 68 FR 37077, June 23, 2003]

§ 3.10 Stay of review time.

Any filing with or review by the product jurisdiction officer stays the review clock or other established time periods for agency action for an application for marketing approval or required investigational notice during the pendency of the review by the product jurisdiction officer.

Subpart B [Reserved]

PART 5—ORGANIZATION

SUBPARTS A–L [RESERVED]

SUBPART M—ORGANIZATION

Sec.
5.1100 Headquarters.
5.1105 Chief Counsel, Food and Drug Administration.
5.1110 FDA public information offices.

AUTHORITY: 5 U.S.C. 552; 21 U.S.C. 301–397.

SOURCE: 75 FR 16354, Apr. 1, 2010, unless otherwise noted.

Subparts A–L [Reserved]

Subpart M—Organization

§ 5.1100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER.[1]

Office of the Chief Counsel.[2]

Office of the Administrative Law Judge.[1]

Office of Women's Health.

Office of Policy, Planning & Budget.[1]

Office of Policy.

Policy Development and Coordination Staff.

Regulations Policy and Management Staff.

Regulations Editorial Section.

Office of Planning.[1]

Planning Staff.

Evaluation Staff.

Economics Staff.

Risk Communication Staff.

Business Process Planning Staff.

Office of Budget.[1]

Office of Legislation.[3]

Office of the Counselor to the Commissioner.[1]

[1] Mailing address: 10903 New Hampshire Ave., Silver Spring, MD 20906.

[2] The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.

[3] Mailing address: 5600 Fishers Lane, Rockville, MD 20857.